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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,201	12/19/2005	Soumitra Roy	UPN-P3067-2	9061

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EXAMINER	
GUZO, DAVID	
ART UNIT	PAPER NUMBER
1636	
MAIL DATE	DELIVERY MODE
05/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,201	ROY ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-19,38,39,41,42 and 44-53* is/are pending in the application.

4a) Of the above claim(s) *42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-19,38,39,41 and 44-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/19/08,3/20/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Election/Restriction

Applicant's election without traverse of Group I, Claims 13-19, 38-39, 41 and 44-53, in the reply filed on 4/2/08 is acknowledged.

Newly submitted claim 42 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claimed method for eliciting an immune response in a host comprising administering a chimeric adenovirus capable of expressing a heterologous antigen from a pathogen defines an advance over the elected invention in that it involves *in vivo* therapeutic administration of the chimeric adenovirus using protocols not required for administration of the recited chimeric adenovirus to cells for non-therapeutic uses.

Accordingly, claim 42 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

35 USC 101 Rejections

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 18-19, 49 and 50 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claimed host cells include human cells which contain the claimed chimeric adenovirus vector wherein the cells can be *in vivo*. The claimed cell is present or is intended to be present in a human being, said cell becoming integrated into the human

being and therefore being an inseparable part of the human itself. The scope of the claim, therefore, encompasses a human being, which is non-statutory subject matter. As such, the recitation of the limitation "non-human" or "host cell *in vitro*" or "an isolated host cell" would be remedial. See 1077 O.G. 24, April 21, 1987.

Obviousness Type Double Patenting Rejections

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-19, 38-39, 41 and 44-53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 11, 12, 14 and 18-23 of U.S. Patent No. 7,291,498 (hereafter the '498 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite chimeric adenoviruses wherein the genomes of said adenoviruses

comprise right and left portions from a first adenovirus and internal regions (hexon, penton, fiber, etc.) for a second adenovirus (which can be from Ad40 or C1, etc.). The instant claims differ from the '498 patent claims in that the instant claims recite that the adenovirus providing the internal regions of the genome is from an adenovirus which is incapable of efficient growth in a selected host cell while the '498 patent claims recite that the adenovirus is not useful for virion production in a selected host cell type. However, the specification of the '498 patent does not appear to differentiate between the two adenoviruses, i.e. an adenovirus which is incapable of efficient growth in a selected host cell has the same characteristics, with regard to the claimed invention, as an adenovirus which is not useful for virion production in said selected host cell. With regard to the claimed methods of producing a gene product or delivering a gene to a target cell comprising infecting the cell with the claimed chimeric adenovirus, the chimeric adenoviruses claimed in the '498 patent are designed to deliver and express a transgene in a target host cell and said use of the claimed chimeric adenoviruses would have been obvious to the ordinary skilled artisan because the chimeric adenoviruses cannot express the heterologous gene unless they are delivered to a suitable host cell.

35 USC 112, 2nd Paragraph Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-19, 38-39, 41 and 44-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 (and dependent claims) are vague in that there is no antecedent basis for the term "said modified adenovirus".

Claims 13 and 44 (and dependent claims) are vague in that adenoviral sequences form the "left terminal end of a first adenovirus" or adenoviral sequences from "the internal region" or adenoviral sequences from the "right terminal end" of the adenovirus. It appears that applicants are referring to the genome of the adenovirus and if this is correct, the claims should be redrafted to indicate this. For example, in Claim 13, part (a), the claim should be redrafted to recite "[a]denovirus sequences of the left terminal end **of the genome** of a first adenovirus".

The instant invention is free of the art. The prior art teaches chimeric adenoviral vectors which comprise the ITRs from one adenovirus serotype and a hexon or penton or fiber encoding gene or portion of said gene from another adenovirus serotype (See for example, Wu et al., J. Virol., 2002, Vol. 76, No. 24, pp. 12775-12782, cited by applicants). The prior art does not teach or suggest chimeric adenoviruses comprising the 5' and 3' terminal regions (i.e. ITRs) from one serotype and the internal region (at least hexon, penton and fiber genes) from another serotype.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D., can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 22, 2008

/David Guzo/
Primary Examiner
Art Unit 1636